SAFER CONSUMER PRODUCTS

Alternatives Assessments:

Examples and Lessons Learned

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Contents

INTRODUCTION

The Department of Toxic Substances Control (DTSC) Safer Consumer Products (SCP) program challenges responsible entities to reduce or eliminate toxic chemicals in consumer products. The SCP regulations (Cal. Code Reg., tit. 22, § 69505 et seq.) establish innovative approaches for DTSC to identify Priority Products containing Chemicals of Concern, and for responsible entities to identify, evaluate, and adopt safer alternatives. Alternatives Analysis – the evaluation and comparison of a Priority Product and one or more alternatives to the product – is a key component of the SCP regulations. In the SCP regulations, the term Alternatives Analysis intentionally differentiates the SCP approach from the contemporary practice of alternatives assessment.

DTSC comprehensively reviewed 13 publicly available examples of alternatives assessments that various industry groups and regulatory agencies developed to evaluate alternatives. DTSC's goal is to identify examples that illustrate various aspects of the SCP Alternatives Analysis regulatory requirements. This exercise helps DTSC better understand the current alternatives assessments practice available to stakeholders. DTSC has summarized general conclusions for each example, including the strengths of each alternatives assessment regarding the requirements of the SCP Alternatives Analysis framework.

Please note that, for the most part, these examples were developed to meet their own objectives rather than the SCP regulatory requirements, and as such, DTSC is analyzing them for their strengths and not to highlight deficiencies.

Important note: This synopsis and the associated example reviews are advisory in nature, informational in content, and intended to assist responsible entities that are conducting an Alternatives Analysis. Our evaluation of examples does not constitute a standard or regulation, and creates no new legal obligation. It does not alter or determine compliance responsibilities set forth in statutory and regulatory requirements.

Methods of Selection and Review of Alternatives Assessment Examples

Each example of an alternatives assessment discussed here represents a completed analysis of alternatives for a problematic chemical in a specified product. Each identifies, evaluates, and compares alternatives, and each offers results, conclusions, and recommendations based on the alternatives evaluated. They also all share the following common characteristics:

- they are available in the public domain at no cost.
- each is sufficiently transparent with respect to methodology and analysis.
- each addresses a variety of topic areas required in the SCP Alternatives Analysis process.
- they represent a variety of alternatives assessment frameworks.
- they represent a variety of industry sectors.
- they represent a variety of manufacturers, nongovernmental organizations (NGOs), or government bodies that prepared the alternatives assessment.

DTSC evaluates these essential topics for the thirteen alternatives assessment examples:

• product requirements • identification of alternatives • identification of relevant factors
• initial screening • hazard (including both human health and ecological toxicity) • exposure
• life cycle impacts • data gaps and uncertainties • economic impacts • decision-making

DTSC uses these criteria to review the examples for:

- transparency and documentation,
- reasoning and justification,
- relevance to SCP Alternatives Analysis requirements, and
- acknowledgment of data gaps and uncertainties.

Because these examples are usually context-specific and conducted for different purposes and follow different alternatives assessment frameworks, DTSC does not critically review each example for:

- comprehensiveness of the assessment,
- suitability of specific tools or models,
- quality of supporting information,
- adequacy of analysis (e.g., explaining the usefulness of data for hazard assessment purposes),
- compliance with SCP Alternatives Analysis requirements, and
- identification of topic areas that are not within the scope of the SCP regulations.

LESSONS LEARNED AND RECOMMENDATIONS FOR IMPROVEMENT

General Observations

The range of alternatives identified, the factors and attributes compared, and the level of detail presented in these alternatives assessment examples vary greatly depending on the type of alternatives assessment framework used, how the problems are defined, and who conducted the assessment. Although DTSC does not critically review the examples for comprehensiveness, DTSC observes that some reports have a narrower scope or are missing elements called for in the SCP Alternatives Analysis framework. For instance, most of the examples consider only chemical replacement alternatives. This is partially because the product's performance and the function of the Chemical of Concern are narrowly defined. Furthermore, most of these examples focus on public health impacts and human health toxicological endpoints but lack an ecological impact assessment. The very limited ecological impact assessments generally cover aquatic impacts only. Even for the examples covering human health hazard assessment, not all the required public health impacts and human health toxicological endpoints in the SCP framework are fully characterized. In addition, there are missing elements in exposure, life cycle impacts, and economic impacts assessments. Finally, none of the examples have explicit decision-making discussions analyzing the trade-offs across technical, environmental, and economic aspects.

These gaps and narrower scope of comparison presented in the examples could be partially explained by a lack of data. DTSC's review of the examples provides some insight into data challenges regarding both data availability and data quality. For example:

- Nonhuman hazard information (ecological hazards and ecotoxicity endpoints) are limited to aquatic impacts, but should include amphibian, avian, and other terrestrial impacts if data are available.
- Exposure data should include emission rates for different use scenarios, worker exposure data, and environmental monitoring data.
- The detailed composition of the product and the potential impacts to human health and the environment should be disclosed.
- A description of the chemical's functional use should be included.
- Life cycle inventory and impact assessment data should be included if available.

The nature of the alternatives assessment framework used also limits the scope of comparison in these examples. For instance, exposure and life cycle impacts assessment are listed as a separate, optional step or element in several frameworks such as the Interstate Chemicals Clearinghouse[1] and the National Research Council[2] alternatives assessment framework. Some earlier alternatives assessment examples tend to assume the exposure and life cycle concerns of replacement chemicals are the same as the Chemical of Concern and focus on hazard assessment only. The others may use exposure and life cycle concerns to prioritize the hazard traits for decision-making and to recommend risk management options for the

[1] *Interstate Chemicals Clearinghouse (IC2). 2017. Alternatives Assessment Guide Version 1.1. Available: http://theic2.org/article/download-pdf/file_name/IC2_AA_Guide_Version_1.1.pdf*

[2] *National Research Council. 2014. A Framework to Guide Selection of Chemical Alternatives. Washington DC: National Academies Press.*

selected alternatives. As a result, assessments presented by these examples generally do not integrate the disparate alternatives assessment elements cohesively and holistically as called for under the SCP regulations.

Specific Observations and Recommendations to Align with SCP Alternatives Analysis

Product requirements

Product requirements include the functional, performance, and legal aspects of a product. Stakeholders ranked this topic as the most important training topic for Alternatives Analysis in an SCP stakeholder survey.

The tools commonly used to address product requirements in the examples include a narrative description of the product system, manufacturing process flow maps, customer claims, industry standards, literature research, and pilot testing on essential performance characteristics. The product-chemical combination usually determines how complex the supply chain is within a specific product sector. A complex supply chain usually makes technical performance evaluation more challenging.

The level of detail presented in the examples describing the product requirements varies by product category or sector and by who conducted the assessment. Assessing the product performance and the function of the Chemical of Concern usually requires deep knowledge of the technical parameters, industry standards, and legal requirements for the product, and of how the Chemical of Concern is used and the function it performed in a product system. It also requires specific expertise on process technology, performance specifications and parameters, industry standards, labeling requirements, and technical feasibility. As a result, third-party practitioners such as government or contract alternatives assessors usually have very limited technical capacity and rely heavily on publicly available information, which limits the completeness of the discussion on product requirements.

To strengthen product requirement discussion, we recommend early planning to coordinate the resources and expertise needed to provide and evaluate information on process design and parameters, chemistry, materials science, engineering, industry standards, and product technical feasibility. Furthermore, the key question to be addressed in the evaluation of the product requirements should be “Is the Chemical of Concern necessary?” The supporting information and rationale should document and define the “necessity” of the chemicals in products and the “viability” of alternatives clearly in the report. More details are discussed in Chapter 2 of DTSC’s Alternatives Analysis Guide (Version 1.0).

Identification of Alternatives

Many of the alternatives assessment examples that DTSC reviewed only focus on chemical replacement, not other types of alternatives. Some reports collect information on available and potential alternatives from a variety of sources, and some rely on only a few.

The full range of alternatives (as specified in Cal. Code Regs., tit.22, § 69501.1, subds. (a)(10)) that must be considered when identifying alternatives includes:

1) removal of Chemical(s) of Concern from a Priority Product, with or without the use of one or more replacement chemicals;
2) reformulation or redesign of a Priority Product and/or manufacturing process to eliminate or reduce the concentration of Chemical(s) of Concern;
3) redesign of a Priority Product and/or manufacturing process to reduce or restrict potential exposures to Chemical(s) of Concern in the Priority Product; and
4) any other change to a Priority Product or manufacturing process that reduces the potential adverse impacts and/or potential exposures associated with the Chemical(s) of Concern in the Priority Product, and the potential adverse waste and end-of-life effects associated with the Priority Product.

In addition, any existing, possibly viable alternatives identified through research, and any identified alternatives from information posted on DTSC's website, should also be considered.

To strengthen the identification of alternatives, we recommend considering the alternatives listed in the Priority Product Technical Profile on the DTSC website and the other types of alternatives listed under the definition of "alternative" in the SCP regulations. We also recommend explaining the rationale for selecting and rejecting specific alternatives. For rejected alternatives where the adverse impacts are equal to or greater than the Priority Product, the method and supporting information used to make this determination should be described. Good examples for this section usually document active stakeholder engagement, comprehensive research to identify alternatives, a scope that included more than chemical replacement, clear documentation of information sources, and justification of selection of alternatives for further evaluation. More details are discussed in Section 2.4 of the Alternatives Analysis Guide (Version 1.0).

Identification of Relevant Factors

Relevant factors are a unique requirement of the SCP Alternatives Analysis process. In performing an Alternative Analysis, responsible entities are required to consider nine factors:

1) adverse environmental impacts which include adverse air, ecological, soil, and water quality impacts;
2) adverse public health impacts;
3) adverse waste and end-of-life impacts;
4) environmental fate;
5) materials and resource consumption impacts;
6) physical chemical hazards;
7) physicochemical properties;
8) product function and performance; and
9) economic impacts.

Each of these factors has several endpoints or properties that must be evaluated as part of the Alternatives Analysis. Most alternative assessments focus on only a subset of the SCP requirements. For instance,

GreenScreen,[3] a comparative chemical hazard assessment methodology for identifying chemicals of high concern, is widely used. However, it characterizes only a subset of the required public health impacts, environmental impacts, physicochemical properties, and physical chemical hazards.

Some ways to strengthen the alternative assessment examples that DTSC reviewed include:

1) evaluating and comparing the Priority Product and alternatives based on the factors listed above,
2) evaluating the impacts of the Priority Product and alternatives based on the life cycle segments defined in the SCP regulations, and
3) evaluating the impacts of the Priority Product and alternatives based on the exposure pathways and factors defined in the SCP regulations.

More details are discussed in Chapter 3 of the Alternatives Analysis Guide.

Hazard (Including Human Health and Ecological Toxicity Endpoints)

Adverse public health impacts and adverse environmental impacts that affect human and ecological receptors respectively, must be considered in the SCP Alternatives Analysis process. Particularly, in the evaluation of adverse public health impacts, 20 toxicological hazard traits (as identified in Cal. Code Regs., tit. 22, § 69401 et seq.) should be considered. Most of the examples consider specific subsets of hazard endpoints or identify the most sensitive toxicological endpoints, but do not attempt to address all 20 required toxicological hazard traits in the SCP framework. For example, GreenScreen endpoints address 11 of the 20 required toxicological hazard traits associated with human health impacts.

In the evaluation of adverse environmental impacts, ecological receptors must be considered. California Code of Regulations, title 22, sections 69404-69404.10 specify 10 environmental hazard traits that affect microbial, plant, and animal receptors in aquatic and terrestrial ecosystems. Most examples focus on acute toxicity in aquatic receptors (e.g., fish) because there are more data and models focusing on aquatic systems in comparison to terrestrial receptors. In cases where chronic ecotoxicity is assessed, it does not identify apical endpoints (i.e., wildlife growth, development, reproduction, or survival impairments). Bioaccumulation potential and persistence are commonly included in the ecological hazard assessments, but these should also be included in the exposure assessment as they are exposure potential hazard traits in California Code of Regulations, title 22, sections 69405.2 and 69405.3, respectively. Overall, the ecological hazard assessment is lacking in the examples reviewed, and DTSC identifies several data gaps.

Clear documentation of the methods used to identify and analyze human and ecological hazard endpoints is important in understanding the findings of the hazard impact assessment. Most examples summarize their approach to identifying key hazard endpoints, but not in a manner that clearly explains their findings or the results can be easily replicated. The documentation should clearly explain the rationale and evaluation criteria used in the human and ecological hazard assessment. In creating a hazard profile for its alternatives assessments, the U.S. Environmental Protection Agency (U.S. EPA) demonstrated the strength of clear documentation in data sources and assessment methodology.

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[3] *GreenScreen for Safer Chemicals is a method for chemical hazard assessment. More details of the methods see https://www.greenscreenchemicals.org/method.*

The hazard assessments could be strengthened by:

1) considering all human and ecological hazard traits (as specified in Cal. Code Regs., tit. 22, § 69401 et seq.) where data is available;
2) increasing transparency on methods and data evaluation (i.e., providing full data summaries of each hazard trait evaluated); and
3) attempting to fill data gaps by generating data through additional research and modeling, or by reviewing primary research in scientific literature.

For ecological hazard assessments, an exposure-driven assessment should help limit the number of potential receptors of interest (i.e., which environmental media are likely to be impacted by the product or the alternatives). More details are discussed in Chapter 4 of SCP's Alternatives Analysis Guide.

Exposure

The SCP Alternatives Analysis process explicitly states that exposure assessments need to be conducted in a comparative way, with the consideration of exposure pathways in each life cycle stage of a product. Although exposure or exposure assessment is mentioned in all the examples reviewed, exposures are not sufficiently assessed (or not assessed at all) in most of the examples.

- First, no comparative exposure assessments are presented in the documents. In some examples, exposure assessments were only conducted for the Chemical of Concern, not for alternatives. In other examples, key factors associated with exposures are simply listed across different products without further assessments.
- Second, exposures are not sufficiently assessed throughout the life cycle of a product. The focus of some exposure assessments is on the use stage of a product, without considering other life cycle segments.
- Third, ecological exposure assessments are not sufficiently conducted. Most examples focus on human exposure assessment, with just a brief discussion of ecological systems, although the SCP regulation requires very specific ecological impacts to be assessed. Bioaccumulation and persistence are two important hazard traits associated with ecological exposure, but they are typically discussed in these examples in the section on adverse environmental impacts, and are not sufficiently discussed in the section on exposures.

Either quantitative or qualitative exposure assessments can be incorporated in several existing frameworks (e.g., the Interstate Chemicals Clearinghouse and U.S. EPA's Design for the Environment Alternatives Assessment Framework). Exposure assessments conducted under these frameworks could be further strengthened:

- For quantitative exposure assessment, the selection of exposure models and input parameters needs to be consistent with exposure scenarios.
- For qualitative and quantitative exposure assessment, rationales, data gaps, and uncertainties need to be addressed.

More details are discussed in Chapter 6 of the Alternatives Analysis Guide.

Life Cycle Impacts

The analysis of multimedia life cycle impacts helps to avoid regrettable substitution that shifts unintended environmental consequences from one life cycle stage to another or from one environmental medium to another. Consideration of multimedia life cycle impacts is a unique requirement mandated by the SCP Alternatives Analysis. Under the SCP regulations, life cycle impacts cover all relevant impacts during the product's entire life span, including raw materials extraction, resource inputs and other resource consumption, intermediate materials processes, manufacturing, packing, transportation, distribution, use, operation and maintenance, waste generation and management, reuse and recycling, and end-of-life disposal.

DTSC's review of the existing alternatives assessment examples finds the scope of the analyses is primarily on the use stage, due to the limited scope of the widely used alternatives assessment frameworks. Very few examples provide a qualitative discussion of either worker exposure during the manufacturing stage or concerns during end-of-life disposal. However, even those do not address all the required multimedia life cycle impacts called for under the SCP regulations.

There are two dominant ways to address multimedia life cycle impacts: life cycle thinking and life cycle assessment. Life cycle thinking is a simplified and usually qualitative way to evaluate relevant changes in the life cycle and associated environmental consequences when comparing alternatives. Life cycle assessment follows a well-defined quantitative methodology, such as the ISO 14040 Standard promulgated by the International Organization for Standardization. The challenge is usually the lack of comprehensive life cycle inventory data (e.g., resource consumption and emissions) and methodology to convert the inventory data into the associated multimedia environmental impacts.

To improve the analysis of life cycle impacts, we recommend:

1) focusing on the identification of relevant life cycle segments and relevant factors (refer to the Alternatives Analysis Guide's Section 3.3 and Chapter 7), and
2) using a streamlined life cycle-based analysis when it is supported by the best available data.

Life cycle thinking and hotspot analysis[4] based on best available information is usually sufficient during the first stage of an Alternatives Analysis. More research can be done during the second stage of the Alternatives Analysis to re-evaluate the relevant multimedia life cycle impacts. The life cycle impacts should be consistent with the associated exposure pathways and the justification for the relevant factors.

Multimedia life cycle impacts analysis also helps to compare nonchemical replacement alternatives (e.g., materials change, process change, or product redesign) based on functional equivalence provided by a product system. It usually requires specific knowledge and stakeholder engagement to collect and evaluate

[4] *Hotspots analysis: a method that allows for rapid assimilation and analysis of a range of information sources, including life cycle-based studies, market, scientific research, expert opinion, and stakeholder concerns. (Source: Barthel M., Fava J.A., Harnanan C.A., Strothmann P., Khan S., Miller S. 2015. Hotspots Analysis: Providing the Focus for Action. In: Sonnemann G., Margni M. (eds.) Life Cycle Management. LCA Compendium – The Complete World of Life Cycle Assessment. Springer, Dordrecht.)*

information along the supply chain. However, it does not necessarily require full control over every single unit operation along the life cycle of a product.

Economic Impacts

Under the SCP regulations, the economic impacts associated with public health costs, environmental costs, and costs to governmental agencies and nonprofit organizations charged with managing or overseeing the environment must be evaluated.

Most of the alternative assessment examples for economic impacts focus on internal costs to the manufacturer. Internal costs are usually based on a cost analysis for a limited set of conditions, and discussion of the assumptions and rationale ranges from minimal to very detailed. Most examples do not discuss socioeconomic costs. The challenge in reviewing the examples is the limited availability of data and methods for estimating socioeconomic costs defined under the SCP regulations.

These discussions could be improved by:

1) expanding the internal cost discussions to include costs associated with waste impacts, such as:
    a. increased or decreased waste generated,
    b. changes in type of waste generated at the manufacturing facility or by end-user,
    c. impacts due to feedstock changes (if any),
    d. labor costs (e.g., additional worker training needed, specialized skill sets), and
    e. engineering control costs;
2) discussing the impacts and benefits associated with a potential process change (e.g., replacing process equipment, reducing exposure for workers) where applicable; and
3) discussing any attempts made to address socioeconomic benefits and costs.

More details are discussed in Chapter 8 of SCP's Alternatives Analysis Guide.

Data Gaps and Uncertainties

Most of the alternatives assessment examples document data gaps and how the data gaps and uncertainty affect decision-making. However, very few examples demonstrate methods to fill data gaps or address any uncertainties regarding hazard, exposure, life cycle impacts, and economic impacts systematically.

The amount of detail provided about data gaps often correlates with the framework the authors applied to conduct their alternatives assessments. Stronger assessments use systematic approaches for addressing data gaps. For example, GreenScreen uses a "data gap" to indicate endpoints with insufficient information to assess hazard, and then incorporates it into the overall benchmark rating system. When measured data are not available in the primary research literature, some examples use Qualitative Structure-Activity Relationships (QSAR) to address data gaps in some examples. In addition, two examples use sensitivity analysis to quantify the impact of uncertainties on decisions.

To improve the analysis of data gaps and uncertainty, we recommend reviewing Chapter 9 of the Alternatives Analysis Guide and other best practice guidance documents, such as the International Organization for Economic Co-operation and Development (OECD)'s Guidance on Grouping of Chemicals.[5]

Applying transparency is the key to improving the analysis on data gaps. This requires:

1) documenting the data gaps and source of uncertainty, and
2) explaining the rationale for making decisions involving data gaps and uncertainty.

Initial Screening and Decision-Making

Many of these alternatives assessment examples either do not include an explicit decision-making section or lack transparency on how decisions are made when data gaps and uncertainties exist. The examples clearly demonstrate the importance of transparency in determining the quality of the assessment. A good alternatives assessment study addresses uncertainty, documents assumptions, provides data sources, describes approaches and tools used, and provides the rationale used to make an informed decision.

We suggest improving the decision-making discussion by including summary tables that explicitly list the criteria and weighting factors (if applicable) used in decision-making for different alternatives assessment elements such as exposure, human health and ecological hazard traits, and life cycle impacts. A matrix, such as a summary table, displaying the qualitative or quantitative trade-off information used in decision-making should be used to provide a clear visual comparison that summarizes the information collected regarding the relevant adverse impacts and their associated relevant exposure pathways and life cycle segments. Chapters 3, 5, 6, and 10 in the Alternatives Analysis Guide have examples for documenting and presenting the results of the decision-making processes.

[5] *OECD. 2017. Guidance on Grouping of Chemicals, Second edition. In OECD series on Testing and Assessment. Available: http://www.oecd.org/publications/guidance-on-grouping-of-chemicals-second-edition-9789264274679-en.htm*

CONCLUSION

Our review of alternatives assessment examples recognizes both the significant similarities between the existing alternatives assessment practice and the SCP Alternatives Analysis framework, as well as the unique SCP requirements. Although there are gaps and challenges identified during the review, we conclude that alternatives assessment is a fast-growing field with rigorous scientific and analytical approaches. Its multidisciplinary nature has led to a high degree of technical collaboration across disciplines and rapid knowledge uptake to continuously refine information and methodologies for alternatives assessment. To align with the efforts in this evolving field, we make the following recommendations to support stakeholders who are conducting SCP Alternatives Analyses with the goal of selecting safer alternatives and avoiding regrettable substitutions:

- The evaluation of product requirements should provide the supporting information and rationale used to address the question "Is the Chemical of Concern necessary?" The assessment should explain the functional use of chemicals and, if asserted, its "necessity," and specify performance attributes and legal requirements for the product.
- The identification of alternatives should go beyond just chemical replacement and consider the viability of removing the Chemical of Concern, reformulation and redesign of the product, and changes in the manufacturing process.
- The scope of comparison factors should be comprehensive enough to consider and address all the potential trade-offs among performance, hazard, exposure, economic impacts, and life cycle impacts required by the SCP regulations. All the information should be incorporated systematically and cohesively to make an informed decision.
- All the evaluations and analyses in the Alternatives Analysis process are comparative in nature. Identification of relevant factors should use available information (quantitative and qualitative) and analytical tools to provide supporting information and explain the rationale for any factors determined not to be relevant for comparison of alternatives.
- The hazard assessment should consider all the relevant human health and ecological toxicological endpoints, and improve documentation on methods and data evaluation.
- The comparative exposure assessment should consider all the relevant human health and ecological exposure factors along the life cycle of the product and alternatives.
- A streamlined life cycle-based analysis using the best available data can help to address multimedia (air, water, soil, and ecological) life cycle impacts, materials and resource consumption impacts, and adverse waste and end-of-life impacts with associated life cycle segments.
- The discussion of economic impacts should focus on relevant exposure pathways and life cycle segments, and demonstrate the efforts made and methods used to compare internal costs, public health costs, environmental costs, and costs to the applicable governmental agencies and nonprofit organizations.
- A matrix or other summary format should be provided for a clear visual comparison that summarizes the information collected regarding the relevant adverse impacts, their associated exposure pathways and life cycle segments, and the comparative results of evaluating this information.

- Any decision made during any stage of the Alternatives Analysis process should explicitly document assumptions, provide data sources, describe approaches and tools, address data gaps and uncertainties, and provide the rationale used to make an informed decision.
- More scientific research efforts should be encouraged to fill in the information gaps and provide rigorous data for the Alternatives Analysis, especially in the field of ecotoxicity, exposure, life cycle impacts, and economic impacts.